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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/004,420	01/08/1998	JACOB RICHTER	260048601	1198

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KENYON & KENYON  
ONE BROADWAY  
NEW YORK, NY 10004

EXAMINER

NASSER, ROBERT L

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/27/2003

27

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/004,420

Applicant(s)

RICHTER ET AL.

Examiner

Robert L. Nasser

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 June 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,5,7-19,24,25,29-37,39,40 and 70-84 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5,7-9 and 11 is/are allowed.
- 6) ☐ Claim(s) 1, 12-19, 24, 25, 29-37, 39, 40, 70-84 is/are rejected.
- 7) ☐ Claim(s) 10 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 12, 13, and 84 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. All of these claims recite a positive relationship between the sensors and then body lumen. The human body is non-statutory subject matter and cannot be positively recited. Therefore, the claims recite non-statutory subject matter. Applicant should amend the claims to recite that when the device is in the lumen, the sensors are spaced apart, or use similar inferential language.

Claims 15-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are rejected in that there is an inconsistency between the body and the preamble of the claim. The preamble states the device is for fixing a sensor in place. It does not positively recite the sensor. Claims 15-18 recite a positive connection between the sensor and the sensor support. Therefore, it is unclear whether the claim is drawn to the combination including the sensor or not. For the purposes of applying art, it will; be treated as being drawn to the combination.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 19, 24, 25, 29, 32, 35, 39, 40, 70-84 are rejected under 35

U.S.C. 102(b) as being anticipated by Anderson et al. Anderson shows a catheter 10 housing a sensor 72a on a sensor support 72c, with a fixation device 50a, where the sensor is connected to the end of the fixation device. Further, the sensor and sensor support are outside of the region of the fixation device, and the sensor and sensor substrate are independently shaped and made from the same material. Anderson shows the remaining claim features. The examiner notes that it is well known to adhesively or sewingly attach a sensor to the body. Therefore, it would have been obvious to modify Anderson to use adhesive or sutures in place of or in addition to the tines 50.

Claims 1, 11, 12, 24, 25, 29, 32, 35-37 70-80 and 82 are rejected under 35

U.S.C. 102(b) as being anticipated by Hickey et al. Hickey et al shows a device including a sensor support. i.e. catheter, carrying a sensor, i.e. sensing balloon, and a fixation device 41, that is adapted to contact the lumen wall. The fixation device is expandable. It further teaches the method of expanding the balloon 41 to fix the sensors in place at the proper location. It has the remaining claim features. With respect to claim 12, Hickey shows a first fixation device catheter 11 and second fixation device balloon 41 which are spaced apart around sensing balloon and its support. The examiner notes that the record does not define what a fixation device is. It is the examiner's position that the catheter like member 11 is attached to equipment externally

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and fixed in place. Applicant might overcome this rejection by further expanding the definition of "fixation device."

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 15-18, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. The examiner notes that with respect to claims 15-18 the exact sensor structure is not for a specific purpose and does not solve a stated problem. As such, the exact sensor shape would have been a mere matter of design choice to one skilled in the art. With respect to claims 30 and 31, the exact method for attaching the sensor to the sensor support would have also been a matter of design choice.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Anderson et al. With respect to claims 30 and 31, the exact method for attaching the sensor to the sensor support would have also been a matter of design choice.

Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. None of the art shows two fixation rings, as claimed.

Claims 5, 7-9, 11, and 13 are allowable. Claims 5 and 7 define over the art in that none of the art has the sinusoid on the anchoring ring, as claimed. Claims 8 and 9

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define over the art of record in that none of the art shows the ellipses on the anchoring ring. Claim 11 defines over the art of record in that none of the art shows a sensor support located between two fixation devices, as claimed. Claim 13 defines over the art of record in that none of the art shows two anchoring rings, as recited

Applicant's arguments filed 6/13/2003 have been fully considered but they are deemed moot in view of the new grounds of rejection.

The examiner notes that Mr. Magistre, applicant's attorney and the examiner attempted to find allowable subject matter in the application. Mr. Magistre proposed amending claim 1 to recite that the fixation device is a cylindrical or ring structure that is capable of expanding. However, it is the examiner's opinion that the balloon 41 of Hickey or the balloon 16 of Segal or 31 of Frisbee meets this limitation.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Frisbee et al and Segal et al show expandable, cylindrical fixation devices. .

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert L. Nasser whose telephone number is (703) 308-3251. The examiner can normally be reached on Mon-Fri, variable hours.

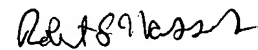
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Robert L. Nasser  
Primary Examiner  
Art Unit 3736

RLN  
August 25, 2003



ROBERT L. NASSER  
PRIMARY EXAMINER